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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/723,476

11/25/2003

Edward J. Gough

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/723,476	Applicant(s) GOUGH ET AL.	
	Examiner Laura A. Bouchelle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 3, 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman (US 6251064) [hereinafter Silverman I] in view of Astarita (US 6228059) in further view of Silverman et al (US 6251063) [Hereinafter Silverman II]. Silverman discloses an injection apparatus comprising a first tubular member 42, a second tubular member 43 slidably received in first member, the distal end of the second tubular member comprises a needle, and a reservoir for a biocompatible composition and a biocompatible solvent (Col. 3, lines 35-40). The biocompatible composition can comprise a biocompatible prepolymer (Col. 6, lines 45-50). Silverman I discloses that an optical element is disposed in the passageway.
3. Claim 1 differs from Silverman I in calling for a locking mechanism to lock the second tubular member with respect to the first tubular member. Astarita teaches an endoscopic instrument having a locking mechanism to lock the inner tubular member relative to the outer tubular member so that the inner tubular member may be fixed safely and easily by a surgeon during complicated procedures (See Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman to include a

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locking mechanism as taught by Astarita so that the inner tubular member may be fixed safely and easily by a surgeon during complicated procedures.

4. Claim 1 further differs from Silverman I in view of Astarita in calling for the device to be sized to be inserted into the passageway of a probe. Silverman II teaches a device similar to that of Silverman I but having the first and second tubular members sized to be received in a probe 22 so that a noninvasive procedure can be performed. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman I in view of Astarita to have the tubular members sized to fit in the lumen of a probe as taught by Silverman II so that a noninvasive procedure can be performed.

5. Claim 2 differs from the teachings of Silverman I in view of Astarita in calling for the needle to be made of metal and the tubular portion to be made of plastic. Silverman II teaches an injection device having a metal needle and a plastic tubular member because such materials provide the required structural characteristics and are easy to manufacture. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman in view of Astarita to have a metal needle and a plastic tubular member as taught by Silverman II because such materials provide the required structural characteristics and are easy to manufacture.

6. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman I in view of Astarita in view of Silverman II as applied to claim 3 above, and further in view of

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Kikawada (US 5637075). Claim 4 differs from the teachings above in calling for a first and second optical element. Claim 5 differs in calling for the optical element to have an inclined end surface. Kikawada teaches a device for observing the inside of a body cavity having a first optical element for supplying light and a second optical element for receiving reflected light that allows for the physician to visualize the body cavity to facilitate proper placement of the medical device (Col. 1, lines 30-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman I in view of Astarita in view of Silverman II to have a first and second optical element as taught by Kikawada the physician can visualize the body cavity to facilitate proper placement of the medical device.

7. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman I in view of Astarita in view of Silverman II as applied to claim 1 above, and further in view of Morrison (US 4609370). Claim 6 differs from the teachings above in calling for the needle to have a distal face inclined at an angle greater than 25 degrees. Claim 7 calls for the angle to be approximately 30 degrees. Morrison teaches a needle assembly having a needle with an angle of approximately thirty degrees to allow for easy insertion into the tissue (Col. 5, lines 20-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman I in view of Astarita in view of Silverman II to have a needle with an incline of approximately thirty degrees as taught by Morrison to allow for easy insertion into the tissue.

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8. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman I in view of Silverman II. Claim 12 differs from Silverman II in calling for the device to be sized to be inserted into the passageway of a probe and a port distal of the proximal opening. Silverman II teaches a device similar to that of Silverman I but having the first and second tubular members sized to be received in a probe 22 and having a port 52 for introducing a biocompatible solvent into the first tubular member so that a noninvasive procedure can be performed. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Silverman I to have the tubular members sized to fit in the lumen of a probe and a port distal of the proximal opening as taught by Silverman II so that a noninvasive procedure can be performed.

Response to Arguments

9. Applicant's arguments filed 11/6/06 have been fully considered but they are not persuasive. Applicant argues that Silverman does not teach the second tubular member having column strength so as not to buckle during puncture of the tissue. Although Silverman is silent on the column strength of the second tubular member, since the needle punctures the tissue it is clear that the tubular member has the strength not to buckle or else the device would be useless.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

LAB


CATHERINE S. WILLIAMS
PRIMARY EXAMINER